

Message Text

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ORIGIN HEW-06

INFO OCT-01 AF-10 ARA-14 EUR-12 EA-12 ISO-00 OES-07
SIG-03 COME-00 /065 R

DRAFTED BY DHEW/FDA: JRWEINROTH, MD:VB
APPROVED BY OES/ENP/EN: WJWALSH, III
DHEW/PHS/OASH/OIH: MKEFAUVER
ARA/ECA:NBOUTON(INFO)
EUR/CE:SKLINGAMAN(INFO)
EA/J:EFEATHERSTONE(INFO)
EUR/NE:WNEWLIN(INFO)
EUR/WE:JDOBBINS(INFO)
EUR/NE:SWORREL(INFO)
EUR/CE:JHURLEY,JR(INFO)
AF/S:JTAYLOR(INFO)
EUR/NE:RWOODS(INFO)
EA/ANP:TWAJDA(INFO)
EA/ROC:DBROWN(INFO)
EUR/WE:BMCKINLEY(INFO)

-----119443 210556Z /13

P 210051Z APR 78
FM SECSTATE WASHDC
TO AMCONSUL SAO PAULO PRIORITY
AMEMBASSY BONN PRIORITY
AMEMBASSY TOKYO PRIORITY
AMEMBASSY THE HAGUE PRIORITY
AMEMBASSY PARIS PRIORITY
AMEMBASSY LONDON PRIORITY
AMEMBASSY BERN PRIORITY
AMEMBASSY PRETORIA PRIORITY
AMEMBASSY STOCKHOLM PRIORITY
AMEMBASSY CANBERRA PRIORITY
AMEMBASSY TAIPEI PRIORITY
AMEMBASSY ROME PRIORITY
AMEMBASSY MADRID PRIORITY
INFO AMEMBASSY BRASILIA PRIORITY
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E.O. 11652: N/A

TAGS:OGEN, ETRD, EIND, TBIO, BR, GW, JA, NL, FR, UK, SZ, SF,

SUBJECT: FDA ADVISORY - DEFECTIVE MEDICAL DEVICE (RECALL
T 69-8

1. FDA ADVISES OF THE FOLLOWING MEDICAL DEVICE RECALL
PRODUCT INVOLVED: OCCLUSION BALLOON CATHETERS, SUPPLIED
ONLY ON PRESCRIPTION, ALL SIZES, INCLUDING CUSTOM-DESIGNED
UNITS ARE INVOLVED. THE BASIC CATHETER CONSISTS OF 2 LUMENS
THE BALLOON LUMEN (USED ONLY TO INFLATE THE BALLOON) AND
THE DISTAL LUMEN (USED TO INJECT VARIOUS CONTRAST DYES OR
OCCLUDING SUBSTANCES). MAJOR USES ARE: (1) TO IMPROVE
CONTRAST IN ARTERIOGRAPHY AND VENOGRAPHY, (2) OCCLUSION
OF BLOOD TO ORGANS FOR BLOODLESS SURGERY (3) TO OCCLUDE
BLOOD TO TUMORS, BY INJECTION OF A SUBSTANCE WHICH
SOLIDIFIES IN THE BLOOD VESSEL SUPPLYING THE TUMOR. THE
CATHETERS ARE PACKAGED INDIVIDUALLY IN A MYLAR/TYVEK BAG
AND ETO STERILIZED. LABELING INDICATES SINGLE USE ONLY.
CATHETERS ARE MANUFACTURED OF POLYETHYLENE AND ARE
PRE-FORMED.

2. PRODUCT IDENTIFICATION: (A) PRODUCT IS MARKETED ONLY
UNDER THE "MEDI-TECH" LABEL. LABEL CONTAINS THE MANU-
FACTURER'S NAME AND COMPLETE ADDRESS. 50 UNITS OF
UNLABELED CATHETERS WERE SHIPPED (IN 1 SHIPMENT) TO
BIOTROL/I, RUE DU FOIN/75140 PARIS/CEDEX 03/France,
THIS FIRM HAD INTENDED TO APPLY THEIR OWN LABELS. THESE
UNITS ARE CURRENTLY BEING HELD BY FRENCH CUSTOMS.
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(B) ALL CATALOG (PRODUCT) NUMBERS ARE INVOLVED. THESE
ARE OB/5/2/65, OB/5/2/100, OB/7/65, OB/7/2/100, OBW/8/2/65.
ALSO INCLUDED ARE THE CUSTOM-DESIGNS, WHICH ALSO USE THE
SAME FORMAT: OB/-/-/. ALL LOT NUMBERS ARE INVOLVED.
THIS INCLUDES ALL STOCK BACK TO THE FIRST PRODUCTION
ON MAY 1976. A TYPICAL MFG. LOT NUMBER READS " 113076"
WHICH TRANSLATES NOVEMBER 30, 1976.

3. MANUFACTURER/RECALLING FIRM: MEDI-TECH DIVISION,
COOPER SCIENTIFIC CORP., 372 MAIN STREET, WATERTOWN,
MA 02172.

4. REASON FOR RECALL RECOMMENDATION: PRODUCT IS BEING
RECALLED DUE TO A PRODUCT FAILURE WHICH RESULTED IN
PATIENT INJURY DURING AN EXPERIMENTAL PROCEDURE. WHILE
AN INVESTIGATIONAL SILICONE-RUBBER OCCLUSION MATERIAL
WAS BEING INJECTED THROUGH THE DISTAL LUMEN OF THE
CATHETER, THE MATERIAL BEGAN TO SOLIDIFY. THE PHYSICIAN
CONTINUED EXERTING PRESSURE. SOMEWHERE WITHIN THE
MAXIMUM PRESSURE RANGE OF THE CATHETER, THE DISTAL/BALLOON
WALL BURST AND MATERIAL FLOWED INTO THE BALLOON LUMEN.
THIS CAUSED OVER-INFLATION OF THE BALLOON WITH SUBSEQUENT

RUPTURE OF THE BLOOD VESSEL. SINCE THE PROCEDURE WAS BEING PERFORMED ON AN INOPERABLE BRAIN TUMOR, THE RUPTURE CAUSED PARALYSIS, THE PATIENT HAS SURVIVED. THE MFR. HAS CONDUCTED PRESSURE TESTING OF SEVERAL NORMAL UNITS AND FOUND THAT SOME OF THESE HAVE BURST AT PRESSURES BELOW THE RECOMMENDED MAXIMUM PRESSURE.

5. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES/ RECIPIENTS TO DETERMINE IF THEY HAVE BEEN ADVISED BY FIRM OF RECALL. RECIPIENTS ARE TO DISCONTINUE USE AND RETURN ANY REMAINING CATHETERS TO FIRM FREIGHT COLLECT. ANY QUESTIONS CONSIGNEES MAY HAVE REGARDING RECALL SHOULD BE DIRECTED TO FIRM WHICH DESIGNATED ROBERT ARCANGELI AS RECALL COORDINATOR.
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6. FOREIGN CONSIGNEES AS FOLLOWS:

SERGIO S. LIMA, MD. KEYMED, LTD.
HOSPITAL SANTA HELENA KEYMED HOUSE
RUS VERGUEIRO, 17 STOCK ROAD
CX POSTAL 30.447 SOUTHEND-ON-SEA SS2 5QH
SAO PAULO, BRAZIL ENGLAND

INGENOR PROF. DR. MED. E. ZEITLER
70 RUE ORFILA FACHARZT FUR RADIOLOGIE
73020 PARIS, FRANCE STADTISCHE KRANKENANSTALTEN
-- FIURSTR. 17
BIOTROL 8500 NURNBERG, GERMANY
1, RUE DU FOIN
75140 PARIS PROF. DR. MED D. NOVAK
CEDEX 03 DIREKTOR DES ZENTRALINSTITUT
FRANCE RONTGENDIAGNOSTIK
-- BRESERSTRABE 79
HENK PRIKKEN D 6700 LUDWIGSHAFEN AM
P.O. BOX 16 RHEIN, GERMANY
RUINERWOLD, HOLLAND

HILEKES, B.V. KLAUS F. MEDENBACH, M.D.
POSTBUS 202 FUNF BAUME WEG 34
BUSSUM 79 ULM-SOFLINGEN
HOLLAND WEST GERMANY

HILEKES GMBH J.H. WEBER, M.D.
4600 DORTMUND 41 DEPARTMENT OF RADIOLOGY
(APLERBECK) GENERAL HOSPITAL ALTONA
POSTKUTSCHENSTRASSE 16 PAUL O EHRLICH-STRASSE 1
GERMANY 2000 HAMBURG-50
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-- WEST GERMANY
HILEKES MEDICAL AG
STEINHAUSERSTRASSE 23 KYOSAKO YAMADA, M.D.
6301 ZUG 1-5-7 AESHINOCHI ABENOKO
SWITZERLAND OSAKO, JAPAN T548

FREDERICK C. MARCUS AND CO. ABBOTT AB
(PTY) LTD. BOX 30064
P.O. BOX 3039 S-104 25 STOCKHOLM
CAPE TOWN 8000 SWEDEN
SOUTH AFRICA

N. STENNING AND CO. (PTY) LTD.
BOX 64
CAMPERDOWN, N.S.W., 2050
AUSTRALIA

MIA-HOU HWANG, M.D. ANDREAS GRUNTZIG, M.D.
MAYWA'S SURGICAL CLINIC CARDIOLOGY
NO. 2 KWANG FU MEDICAL POLYCLINIC
CHANG HUA CITY RAMISTRASSE 100, CH-8006
REPUBLIC OF CHINA ZURICH, SWITZERLAND

, PLINIO ROSSIM.D. MEDICAL EUROPA
UNIVERSITY OF ROME VIA AGUSTA 158
POLICLINICO UMBERTO PRIMO BARCELONA 6
ROME, ITALY SPAIN CHRISTOPHER

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NNN

Message Attributes

Automatic Decaptioning: Z
Capture Date: 01 jan 1994
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Current Classification: UNCLASSIFIED
Concepts: MEDICAL EQUIPMENT, RECALLS
Control Number: n/a
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Draft Date: 21 apr 1978
Decaption Date: 20 Mar 2014
Decaption Note: 25 YEAR REVIEW
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 jan 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
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Document Unique ID: 00
Drafter: JRWEINROTH, MD:VB
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D780170-0692
Format: TEL
From: STATE
Handling Restrictions:
Image Path:
ISecure: 1
Legacy Key: link1978/newtext/t19780430/aaaaazaf.tel
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Litigation History:
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Original Previous Classification: n/a
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Review Media Identifier:
Review Release Date: N/A
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 2889848
Secure: OPEN
Status: NATIVE
Subject: ECT: FDA ADVISORY - DEFECTIVE MEDICAL DEVICE (RECALL T 69-8
TAGS: OGEN, ETRD, EIND, TBIO, BR, GE, JA, NL, FR, UK, SZ, SF, US, FDA
To: SAO PAULO BONN MULTIPLE
Type: TE
vdkgvwkey: odb://SAS/SAS.dbo.SAS_Docs/f20aefa9-c288-dd11-92da-001cc4696bcc
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20 Mar 2014
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